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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/432,820 11/02/99 KAPOOR

A A-57004-4/RF

HM22/0130

EXAMINER

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ZARA, J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

01/30/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/432,820	KAPOOR ET AL.
	Examiner Jane Zara	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 27 December 2000.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 24-49 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 24-49 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

19) Notice of Informal Patent Application (PTO-152)

20) Other: *Notice Statement*.

File

## **DETAILED ACTION**

Claims 24-49 are pending in the instant application.

### *Election/Restriction*

Applicant's election with traverse of Group I, claims 24-33 and 41-49, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that examination of both Groups I and II, drawn to methods of detecting Mycobacteria comprising detecting polypeptides, or comprising detecting polynucleotides, respectively, would not be a serious burden to the examiner, and traversal is also on the grounds that Applicants are not aware of any relevant references not already cited in the IDS. This is not found persuasive because the subject matter of the two groups comprises methods and compositions which are chemically, functionally, biologically and structurally distinct from each other, and require separate searches and considerations which would not be coextensive. Furthermore, the examiner cannot rely on Applicants' assertion in their response to the restriction requirement, filed January 4, 2001, Paper No. 8, that all possible related subject matter has probably been provided by Applicants, since Applicants, in their information disclosure statement (IDS) filed May 30, 2000, Paper No. 6, specifically state that the submission of the documents in the IDS "shall not be construed as an admission that a search has been made or that better art does not exist". The acceptance of the assumption that that all possible related subject matter has probably been provided by Applicants would preclude performing a thorough and unbiased search by the examiner.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 34-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

*Specification*

The disclosure is objected to because of the following informalities: On page 11 of the specification, a membrane associated polypeptide of a mycobacterium is defined as "any Mycobacterial membrane associated polypeptide which is capable of detecting an immune response against the wild type Mycobacterium containing the membrane associated polypeptide". This is an unclear definition, since a polypeptide can't be capable of detecting an immune response. Perhaps "detecting an immune response" should be replaced with --eliciting an antibody response--.

Appropriate correction is required.

*Sequence Compliance*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. No CRF has been submitted with the instant application. See the accompanying Notice to Comply

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and Sample Statement to use a CRF from a parent application. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-33 and 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the revised guidelines for written description, revised December, 1999. The specification does not describe elements which are essential to various functions of the claimed invention, which elements include those which are essential to the definition of "antigenic determinant". The specification does not describe the elements which are essential to the genus antigenic determinant, nor does the specification describe the elements which are essential to the genus comprising a homologue of SEQ ID No: 2. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising antigenic determinants of SEQ ID NO: 2, nor the distinguishing attributes comprising the genus homologues of SEQ ID NO: 2. The disclosure does not clarify what the common attributes are encompassed by antigenic determinants, nor the common attributes which

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are encompassed by homologues of SEQ ID NO: 2. Thus, the scope of the claims includes numerous structural variants, and the genera are highly variant, because a significant number of structural differences between members of a given genus is permitted. Concise structural features that could distinguish structures or sequences within a genus from others are missing from the disclosure. No common structural attributes identify the members of the genus comprising antigenic determinants of SEQ ID NO: 2, whereby an antigenic distinction exists between antigenic regions of SEQ ID NO: 2 and other homologous bacterial ion motive ATPases. No common structural attributes identify the members of the genus comprising homologues of SEQ ID NO: 2, which homologues are antigenically distinct from other homologous of ion motive ATPases. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in each genera such that the common attributes or characteristics concisely identifying members of each proposed genera are exemplified, and because each genus is highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the various genera claimed. Thus, Applicants were not in possession of the claimed genera.

Claims 24-33 and 41-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of antibodies to *Mycobacterium bovis* and *M. tuberculosis*, does not reasonably provide enablement for a method

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of detecting the presence of antibodies to all *Mycobacteria*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods of detecting the presence of antibodies to any and/or all *Mycobacteria* in a biological sample comprising combining said sample with the protein comprising SEQ ID NO: 2, whereby antibody binding to SEQ ID NO: 2 is detected.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

**The state of the prior art and the predictability or unpredictability of the art.** The instant specification discloses difficulties which exist in attempts to generate methods of immunodiagnosing *Mycobacteria*, which difficulties include a lack of sensitivity and specificity in detecting *Mycobacterial* antigens, and whereby such shortcomings are due to inaccessibility of antigens and host immune suppression due to immunomodulatory cell wall constituents of *Mycobacteria*. Furthermore, methods of detecting clear antigenic distinctions between various *Mycobacterial* strains are lacking in the art for the reasons cited above and because antigenic homologues have been identified among some strains of *Mycobacteria*. (See pages 2-6 of the instant specification.)

**The amount of direction or guidance presented in the specification AND the presence or absence of working examples.** Applicants have not provided guidance in the specification toward a method of detecting the presence of antibodies to any and/or all

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*Mycobacteria*, nor of discerning between the presence of different strains of *Mycobacteria* comprising the detection of antibodies in a sample, which antibodies bind to SEQ ID NO: 2.

The specification teaches the detection of antibody binding to the purported translation product comprising SEQ ID NO: 2, which antibodies have been obtained from patients which have been exposed to *Mycobacterium tuberculosis*. The specification fails to teach the successful detection of all *Mycobacterial* strains upon antibody binding to SEQ ID NO: 2. One skilled in the art would not accept on its face the examples given in the specification of antibody detection upon binding to a translation product obtained from the expression of *M. bovis* genomic library fragments, whereby the presumed translation product comprises SEQ ID NO: 2, and which antibodies are obtained from patients exposed to *M. tuberculosis*, as being correlative or representative of the ability to detect antibodies directed to any and/or all *Mycobacterial* strains in view of the lack of guidance in the specification and known unpredictability associated with the antigenic distinctions or antigenic similarities which exist between various *Mycobacterial* strains whereby antibodies which are generated in an individual upon exposure to *M. tuberculosis*, and also bind to the purported translation product SEQ ID NO: 2, also bind in a quantitatively or qualitatively detectable manner to antibodies directed to all *Mycobacterial* strains. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the ability to detect antibodies directed to any and/or all *Mycobacteria*, whereby such antibodies also bind SEQ ID NO: 2. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art

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associated with the ability to discern between the antigenicity of the various strains of *Mycobacteria*.

**The breadth of the claims and the quantity of experimentation required.** The breadth of the claims is very broad. The claims are drawn to methods of detecting antibodies which bind to any and/or all *Mycobacteria* comprising combining a biological sample with the purported translation product SEQ ID NO: 2, whereby antibody binding to SEQ ID NO: 2 is detected. In order to practice the invention over the scope claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to the detection of antibodies to any and/or all *Mycobacteria* comprising the detection of antibody binding to SEQ ID NO: 2. The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of the ability to detect antibodies which bind to any and/or all *Mycobacteria*, which antibodies also bind to SEQ ID NO: 2. The specification teaches only the ability to detect antibodies which were obtained from patients exposed to *Mycobacterium tuberculosis*, which antibodies also bound to the translation product of the genomic fragment obtained from *M. bovis* as described in the instant specification, which translation product is purportedly SEQ ID No: 2. Since the specification fails to provide any particular guidance for the successful detection of antibodies which bind to all *Mycobacterial* strains comprising the detection of antibodies which bind to SEQ ID NO: 2, and since determination of the ability of a particular antibody generated against a particular strain of *Mycobacteria* to also bind to the purported amino acid sequence comprising SEQ ID NO: 2 is

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highly unpredictable, it would require undue experimentation to practice the invention over the scope claimed.

***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

January 28, 2001



ANDREW WANG  
PATENT EXAMINER  
TCL1600